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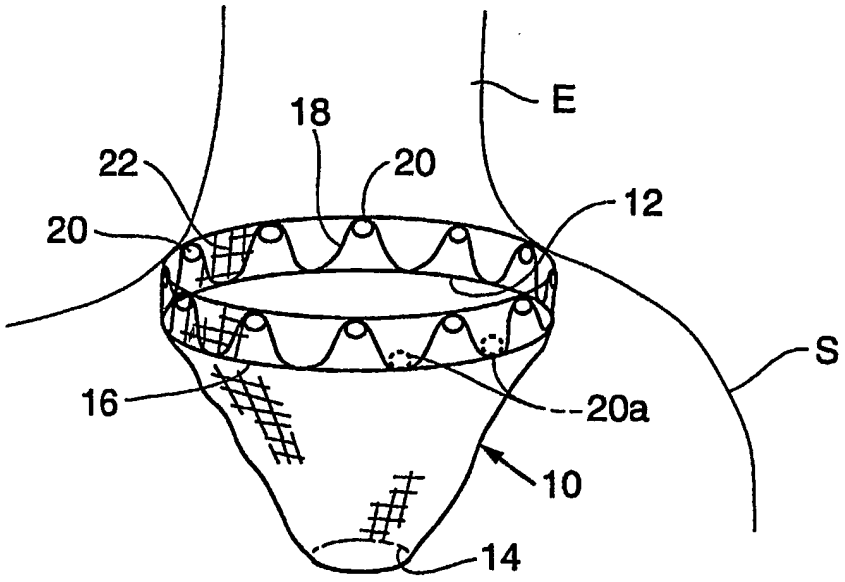
(54) Title: SATIATION IMPLANTS AND METHODS OF USE



(57) Abstract: A pouch positionable within the gastro-esophageal region of a patient, such as for use as a satiation device, is described herein. The pouch includes a proximal opening (12) and an exit port (14), and is positionable such that food ingested by the patient passes into the interior of the pouch and subsequently out the exit port. A barrier (16, 22) on the proximal portion of the pouch contacts surrounding tissue and thereby minimizes passage of food from the esophagus around the exterior of the pouch - thereby substantially preventing food from bypassing the pouch. In preferred forms of the embodiment, the barrier is adaptable in response to movement of the surrounding tissue to maintain contact between the barrier and the surrounding tissue.

WO 2004/064680 A1

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SATIATION IMPLANTS AND METHODS OF USE

Field of the Invention

The present invention relates generally to the field of devices and methods for achieving weight loss in humans, and specifically to the use of devices implantable within the human stomach for controlling feelings of hunger and/or limiting food intake.

Background of the Invention

An anatomical view of a human stomach S and associated features is shown in Fig. 1A. The esophagus E delivers food from the mouth to the proximal portion of the stomach S. The z-line or gastro-esophageal junction Z is the irregularly-shaped border between the thin tissue of the esophagus and the thicker tissue of the stomach wall. The gastro-esophageal junction region G is the region encompassing the distal portion of the esophagus E, the z-line, and the proximal portion of the stomach S.

Stomach S includes a fundus F at its proximal end and an antrum A at its distal end. Antrum A feeds into the pylorus P which attaches to the duodenum D, the proximal region of the small intestine. Within the pylorus P is a sphincter that prevents backflow of food from the duodenum D into the stomach. The middle region of the small intestine, positioned distally of the duodenum D, is the jejunum J.

Prosthetic devices for use in controlling obesity are shown and described in U.S. Application No. 09/940,110, filed August 27, 2001 and U.S. Application No. 10/118,289 filed April 8, 2002, and U.S. Provisional Application No. 60/379,306 filed May 10, 2002. These applications are owned by the assignee of the present application, and the disclosures of these applications are incorporated herein by reference. Certain forms of these devices involve positioning a prosthetic pouch in the proximal stomach as shown in Fig. 1B. The pouch 2 includes a proximal opening 4 and a smaller distal opening 6 and forms a small reservoir that collects masticated food from the esophagus – thereby limiting the amount of food that can be consumed at one time. As the pouch fills with food, it may distend, imparting pressure against the upper stomach and lower esophageal sphincter causing the patient to experience sensations of fullness. The pouch may

additionally or alternatively act as a restrictor, limiting the amount of food intake. The pouch is fixed in place using clips, sutures, suitable adhesives or other means 8 at anchor points around the perimeter of the proximal opening 4.

Because of the flexible nature of the tissue of the gastro-esophageal junction region and/or the material forming the pouch, gaps 9 can occur along the perimeter of the pouch in regions between neighboring anchor points. Solving this problem is made more difficult by the flared geometry of the walls of the proximal stomach. Food entering or accumulating in the pouch 2 can ooze from these gaps and pass around the exterior of the pouch directly into the stomach, thereby decreasing the effectiveness of the prosthesis. The embodiments described herein optimize the function of the pouch devices by forming a barrier against passage of food through any such gaps and/or by eliminating such gaps.

Summary of the Invention

The present invention includes a prosthetic device positionable within the gastro-esophageal junction region of a patient, wherein the prosthetic device includes a proximal opening and a barrier device defining a central passage at least partially aligned with the proximal opening of the prosthetic device. In a method for positioning the prosthetic device, the prosthetic device is attached to tissue of the gastro-esophageal region of the patient, with the device positioned such that food ingested by the patient passes from the esophagus through the central passage and proximal opening into the interior of the prosthetic device. The barrier contacts surrounding tissue and thereby minimizes passage of food from the esophagus around the exterior of the prosthetic device. In preferred forms of the embodiment, the barrier is adaptable in response to movement of the surrounding tissue to maintain contact between the barrier and the surrounding tissue.

Brief Description of the Drawings

Fig. 1A is a schematic illustration of a human stomach and a portion of the small intestine.

Fig. 1B is a perspective view of a satiation pouch provided without supplemental barrier features. The pouch is shown positioned in the stomach.

Fig. 1C is a top plan view of the satiation pouch of Fig. 1B shown within the stomach, and illustrating formation of gaps around the perimeter of the proximal opening.

Fig. 2 is a perspective view of a first embodiment of a pouch having a circumferential barrier. The pouch is shown positioned in the stomach.

Fig. 3 is a perspective view similar to Fig. 2 showing expansion of the barrier into contact with tissue in a stomach having relatively broad proximal dimensions.

Fig. 4A is a top view of a pouch similar to the pouch of Fig. 2 showing the barrier and spring members restrained in a radially inward orientation.

Fig. 4B is a side elevation view of the pouch of Fig. 4A.

Fig. 5 is a perspective view similar to Fig. 2 showing a second embodiment having an alternative barrier configuration utilizing blade members.

Fig. 6 is a perspective view similar to Fig. 2 showing a third embodiment having yet another barrier configuration utilizing a band of stent material.

Fig. 7 is a perspective view similar to Fig. 2 showing a fourth embodiment having yet another barrier configuration utilizing leaf springs.

Fig. 8A is a cross-sectional side elevation view of a fifth embodiment of a pouch, which has a proximal rim that forms a circumferential seal with adjacent body tissue.

Figs. 8B and 8C are cross-sectional side elevation views similar to Fig. 8A showing slight modifications to the rim position.

Fig. 9A is a side elevation view of the pouch of Fig. 8A, showing the rim in the inverted position.

Fig. 9B is a side elevation view similar to Fig. 9B, showing the rim moved to the non-inverted position and drawing tissue over a portion of the rim.

Fig. 10A is a side elevation view of an alternative to the pouch of Fig. 9A, showing the rim in an everted position.

Fig. 10B is a side elevation view similar to Fig. 10B, showing the rim moved to the non-everted position and drawing tissue inside a portion of the rim.

Fig. 11 is a schematic illustration showing a sixth embodiment of a pouch, which utilizes a bellows structure to create a barrier.

Fig. 12 is a schematic illustration showing a seventh embodiment of a pouch, which utilizes a conformable sealing ring.

Fig. 13 is a schematic illustration showing an eighth embodiment of a pouch, which utilizes an inflatable sealing ring.

Fig. 14 is a schematic illustration showing a ninth embodiment of a pouch having an expandable barrier stent.

Fig. 15 is a schematic illustration shown a tenth embodiment of a pouch showing an alternative configuration of a barrier stent.

Detailed Description of the Drawings

The drawings show a number of embodiments of satiation pouches having features that create a barrier against passage of food through gaps occurring between the upper perimeter of the pouch and adjacent tissue and/or that minimize or eliminate such gaps. Ideally, the barriers will form a seal with the adjacent tissue, however it is sufficient that the barriers prevent a substantial amount of food from passing between the exterior of the pouch and adjacent tissue, without necessarily forming an impermeable seal.

For the purposes of this application, the term "satiation devices" or "satiation pouches" will be used to mean devices or pouches intended to induce weight loss in one or more of a variety of ways. These include, but are not limited to, physically restricting the amount of food that can be consumed, and/or imparting pressure against portions of the body (e.g. stomach, esophagus, esophageal sphincter, etc) causing the patient to experience sensations of fullness, and/or affecting levels of hormones or other substances in the body that control or affect feelings of hunger, and/or affecting the amount of ingested food absorbed by the body.

The pouch of each described embodiment may be formed of a flexible material that will prevent passage of food through the sides of the pouch. Examples of such materials include, but are not limited to polyesters (e.g. Dacron® polyester), ePTFE fabric (e.g. GoreTex® fabric or others), a polyurethane such as ChronoFlex® polyurethane, nylon fabrics, silicone, other polymeric materials, and bio-absorbable materials (e.g. PLLA, PGA, PCL, poly-amhydride etc). The material may be a composite of compliant, semi-compliant and/or non-compliant materials that give different regions of the pouch different degrees of compliance so as to allow/limit expansion of the pouch in various locations. For example, it may be desirable to provide the pouch with a fairly elastic exit port to as to prevent occlusion in the event a large piece of food is ingested and/or to control the exit pressure of food from the pouch, whereas the proximal end of

the pouch may be stiffer to prevent bulging. Varying degrees of compliance may also be built into the pouch by varying the cross-sectional thickness in different regions of the pouch. The material may be coated with a lubricious, bio-compatible, chemically inert material, such as paraleyne, to reduce friction on the base material's surface which will help prevent sticking and food build up on the device.

The flexible pouch material may be reinforced with, constructed of, or supported by supporting members, such as a soft mesh, a cage structure, ribs, rings etc. The supporting members may be formed of stainless steel, polymer, shape memory materials such as nitinol, shape memory alloys, or shape memory polymers, or thickened regions of material. The pouch may be constructed so as to be self-expanding, such that the pouch springs radially open into an expanded condition upon ejection from a deployment device or catheter.

Implantation of the described devices is preferably performed endoscopically, by passing the devices through the esophagus, preferably under endoscopic visualization. Alternatively, the devices may be implanted using surgical or laparoscopic procedures.

During implantation the pouch is secured at the gastro-esophageal junction region G using sutures, clips, adhesives, stents or stent-like structures, or other suitable means. One suture attachment device found useful for applying sutures between the pouch and tissue is the "Sew-Right" suturing device available from LSI Solutions of Victor, New York,. Although the pouch may be secured to the esophageal tissue, it is more preferable to apply sutures/clips below the Z-line to allow for attachment to the thicker tissue of the stomach wall.

Each of the described pouches includes a proximal opening and a distal exit port (see openings 4 and 6, respectively, of Fig. 1B). Because of its small volume (which may be on the order of approximately 2 cc-300cc in volume, but is preferably in the range of 10-30 cc), the pouch functions to limit the amount of food that can be consumed at one time. Over time the food within this reservoir descends into the stomach through the exit port.

First Embodiment

Figs. 2 and 3 show a first embodiment of a pouch 10 having a proximal opening 12, distal exit port or opening 14 and a passage extending between the proximal and distal openings.

A resilient ring 16 surrounds the proximal opening 12 and a plurality of spring members 18 are attached to the ring 16. Spring members 18 are preferably biased in a radially outward direction and can pivot relative to ring 16. Although spring members 18 are preferably moveable independently of one another, they may take the form of multiple fingers formed along a single length of wire.

Anchor loops 20 are positioned on the spring members 18. The anchor loops 20 serve to receive sutures, clips or other attachment devices used to connect the pouch to surrounding tissue. The loops in each of the embodiments described in this application should be considered optional, since the pouch may alternatively be anchored directly to the tissue without the use of the loops 20.

The anchor loops 20 may be positioned in the outer apexes of the spring members as shown, and/or they may be positioned elsewhere such as closer to the ring 16. See, for example, loops 20a shown in dashed lines in Fig. 2. Ring 16, spring members 18 and loops 20 are preferably made of a resilient material (e.g. stainless steel, polymers etc.) suitable for use within the body.

Webbing 22 is connected to the spring members 18 along the circumference of the ring 16 to form a skirt-like member having a central opening. Webbing 22 is preferably formed of a flexible material that is substantially impermeable to masticated food. The material may be inelastic or elastic. Examples of suitable materials for the webbing 22 include those listed above for use with the pouch. When the pouch is secured within a patient, the webbing forms a barrier against passage of food between the pouch and surrounding tissue, and directs food into the proximal opening of the pouch. The webbing 22 and spring members 18 are preferably configured to form a dynamic seal with the surrounding tissue, so as to maintain a substantially consistent barrier despite stomach movement and flexure of the pouch. For example, the webbing 22 may be made expandable by using an elastic material and/or by including pleats in the webbing that allow for expansion. Also, the spring members 18 are preferably independently moveable and thus contribute to the dynamic nature of the barrier. In one variation on the first embodiment, the ring 16 and/or spring members 18 may be eliminated and the material of

the webbing 22 itself may provide the necessary spring properties. In such an example, both the pouch and webbing, or the webbing along, may be formed of a resilient silicone or other resilient material.

During use, pouch 10 is introduced into the stomach S via the esophagus E and is held in the desired attachment location in the gastro-esophageal junction region. The pouch is anchored in place such as by connecting sutures or other attachment means to plurality of the anchor loops 20/20a or directly to the pouch and/or webbing to secure the pouch 10 in position. The outward radial forces of spring members 18 cause the spring members 18 to extend radially outwardly, carrying the webbing 22 into contact with the surrounding tissue, creating a barrier that minimizes passage of food around the pouch. If required by the anatomy of the patient's stomach, the spring members 18 will cause the webbing 22 to flare outwardly into contact with the surrounding tissue as shown in Fig. 3. Similarly, a narrower proximal stomach may restrict outward movement of the spring members 18 such that they angle the webbing in a slight inward direction.

If desired, the spring members 18 may be held in a laterally inward position as shown in Figs. 4A and 4B during positioning of the pouch within the stomach. For example, temporary sutures 24 may be threaded through loops 20 and cinched to draw spring members 18 into the position shown in Fig. 4A. As illustrated in Fig. 4B, when drawn inwardly the spring members 18 and webbing 22 may have a relatively flat profile. The pouch may be anchored into position with the spring members 18 and pouch in the inward position, such as by attaching sutures to the loops 20 as described above, or by attaching sutures to additional anchor loops 26 that are separate from the spring members 18. Once the pouch has been sutured into place, temporary sutures 24 are snipped so as to release spring members 18, allowing the spring members 18 to carry the webbing into contact with the surrounding tissue.

Second Embodiment

A second embodiment of a pouch 30 is shown in Fig. 5. The second embodiment differs from the first embodiment primarily in that a plurality of blades 32 are mounted to resilient ring 34. Blades 32 may be formed of a variety of materials, including those listed above for forming the pouch. The blades are outwardly biased using wire reinforcements or other biasing structure. Anchors 36 are preferably positioned in spaced-

apart locations between the blades 32. The pouch 30 is sutured in place by attaching sutures between anchors 36 and adjacent tissue. The blades 32 spring outwardly into contact with surrounding tissue, thereby creating a seal or barrier against passage of food that might otherwise pass between gaps forming between anchor points.

Third Embodiment

Fig. 6 shows a third embodiment of a pouch 40, which uses an expandable stent-like band 42 for creating a seal or barrier. Band 42 is outwardly biased and may be formed of self-expanding material, such as stainless steel or a shape memory material such as nitinol or shape-memory polymer, and may be formed as a soft mesh or other framework formed of such materials in combination. The mesh may be created to have sufficiently small spaces between strands to form an effective barrier against a substantial portion of the ingested food, or it may be provided with a polymeric barrier that prevents ingested food from passing through the walls of the band 42. For example, the polymeric barrier may be a skin formed on the exterior or interior of the mesh, or the mesh may be encapsulated in polymeric material or the polymer may be disposed in the interstices of the mesh.

During use, the pouch 40 is secured in place by attaching sutures between anchors 44 and adjacent tissue of the gastro-esophageal junction region. Band 42 then expands into contact with the surround tissue to form the seal or barrier. The band 42 is preferably positioned beyond the lower esophageal sphincter (identified as LES in Fig. 6) to avoid interference with proper sphincter function.

Fourth Embodiment

A fourth embodiment of a pouch 50, shown in Fig. 7, is similar to the previously described embodiments except that a plurality of leaf springs 52 are attached at the proximal end of the pouch. Springs 52 are outwardly biased to create the seal or barrier with surrounding tissue. As with prior embodiments, the pouch may include a resilient ring 54, and the pouch may be attached to surrounding tissue using sutures passed through anchors 56. In an alternative configuration, springs 52 may be coil springs which may be connected to a common structure at their proximal ends, or which may have free proximal ends.

Fifth Embodiment

Referring to Fig. 8A, a fifth embodiment of a pouch 60 includes an enlarged rim 62 surrounding the proximal opening 64 of the pouch 60. Rim 62 may extend slightly outwardly from the external surface of the pouch as shown in Fig. 8A, or slightly inwardly as shown in Fig. 8B, or both as shown in Fig. 8C. In one form of the fifth embodiment, anchor loops 66 extend from a distal portion of the rim 62 as shown in Fig. 8A. Before the pouch 60 is fixed within the body, the rim 62 is inverted inside the pouch 60 to the position shown in Fig. 9A. Once the rim has been inverted, anchor loops 66 extend in a proximal direction as shown. The pouch 60 is inserted into the stomach and the anchor loops 66 are secured to tissue using sutures or other attachment means. Next, the rim 62 is returned to the non-inverted position shown in Fig. 9B, causing the anchor loops 66 to return to the distally-oriented position. The loops 66 pull the attached tissue in a distal direction, around the edges of the rim 62, creating a taut and leak-resistant seal around the rim.

In another form of the fifth embodiment, anchors 66 extend distally on an interior portion of the rim as shown in Fig. 8B. According to this form of the embodiment, before the pouch is fixed within the body, the rim 62 is everted outside the pouch 60 to the position shown in Fig. 10A – causing anchor loops 66 to extend in a proximal direction as shown. The pouch 60 is inserted into the stomach and the anchor loops 66 are secured to tissue using sutures or other attachment means. Next, the rim 62 is returned to the non-everted position shown in Fig. 10B, causing the anchor loops 66 to return to the distally-oriented position. The loops 66 pull the attached tissue in a distal direction, inside the edges of the rim 62, again creating a seal around the rim.

Sixth through Eighth Embodiments

Fig. 11 shows a sixth embodiment of a pouch 70, which includes an expandable bellows structure 72, attached to a resilient ring 74. Bellows structure 72 includes a central channel 76 in alignment with the proximal opening (not shown) of the pouch 70, and is preferably formed of a flexible material that is substantially impervious to masticated food, and may be formed of materials similar to those listed for use in constructing the pouch. It may have a substantially cylindrical shape or a tapered

geometry such as that shown in Fig. 11. At the proximal end of the bellows structure 72, surrounding the central channel 76, is a sealing ring 78 formed of a flexible material capable of forming a seal when urged into contact with body tissue.

Anchors 79 are attached to resilient ring 74 and are used to receive sutures, clips, etc that will connect the pouch to surrounding body tissue. Once the pouch has been fixed within the stomach, the bellows structure 72 expands the sealing ring 78 into contact with surrounding tissue, thereby creating a barrier or seal. As with prior embodiments, the resilience of the bellows allows the seal to be maintained despite movement of the stomach or expansion of the pouch.

Similar embodiments are shown in Figs. 12 and 13. In the seventh embodiment of Fig. 12, the proximal portion of the pouch 80 includes a conformable sealing ring 82 made of foam, sponge, silicone, or other conformable material that will seal against surrounding tissue when pressed into contact with the tissue. Ring 82 includes a central channel 84 and may include a cylindrical or tapered geometry. Anchors 86 receive sutures or clips used to fix the pouch to body tissue.

The eighth embodiment of Fig.13 is a pouch 90 having a conformable sealing ring 92. Sealing ring 92 is formed of an elastic or inelastic bladder inflatable using an inflation fluid or gas. The bladder may be inflated prior to insertion into the stomach, or it may include a detachable inflation valve (not shown) that may be used to introduce inflation medium into the bladder after the pouch has been fixed within the stomach. As with the seventh embodiment, the sealing ring 92 may have a cylindrical or tapered geometry. Ingested food flows through a central channel 94 in the sealing ring 92 and into the pouch 90.

Ninth and Tenth Embodiments

Figs. 14 and 15 show ninth and tenth embodiments, respectively, of pouches having barrier devices for minimizing passage of food around, rather than through, the pouch. These embodiments are similar to the Fig. 6 embodiment in that they utilize a stent-like structure to expand against surrounding tissue to create the barrier or seal.

The barrier provided with the pouch 100 of Fig. 14 differs from that of Fig. 6 in that band 102 of stent material extends further into the esophagus, creating a seal with the tissue of the esophagus. This seal may be above, below, or within the lower esophageal

sphincter (LES). As with each of the prior embodiments, anchors 104 receive sutures or clips that are used to fix the device to tissue in the region.

In the tenth embodiment shown in Fig. 15, a flexible tubular member 114 extends between the band 112 of stent material and the pouch 110. During use, member 114 may be positioned within the LES region while still preserving function of the LES.

Various embodiments of satiation devices have been described herein. These embodiments are given by way of example and are not intended to limit the scope of the present invention. It should be appreciated, moreover, that the various features of the embodiments that have been described may be combined in various ways to produce numerous additional embodiments. Also, while various materials, dimensions, shapes, implantation locations, etc. have been described for use with disclosed embodiments, others besides those disclosed may be utilized without exceeding the scope of the invention. Lastly, while the pouches have been described for use in controlling feelings of hunger, the barrier devices described herein may be equally suitable for use with other prosthetic devices positionable within the body, including prosthetic valves implanted in the lower esophagus or proximal stomach for controlling gastro-esophageal reflux disease (GERD).

WE CLAIM:

1. A method of positioning a prosthetic device within a patient having an esophagus, a stomach, and a gastro-esophageal junction region, the method comprising the steps of:

providing a prosthetic device having a proximal opening and an exit port, and a barrier on a proximal portion of the prosthetic device, the barrier having a central passage at least partially aligned with the proximal opening;

securing the prosthetic device within a patient by attaching the prosthetic device to tissue of the gastro-esophageal region of the patient, the prosthetic device oriented such that food ingested by the patient passes from the esophagus through the central passage and proximal opening into the interior of the prosthetic device; and

causing the barrier device to contact surrounding tissue, the barrier minimizing passage of food from the esophagus around the exterior of the prosthetic device and into the stomach.

2. The method of claim 1, wherein the barrier includes flexible webbing defining the central passage.

3. The method of claim 2, wherein the flexible webbing includes a resilient spring structure, and wherein the causing step includes allowing the spring structure to move radially outwardly, carrying the webbing into contact with the surrounding tissue.

4. The method of claim 1, wherein the barrier includes a plurality of spring members defining the central passage and spring biased in a radially outward direction, and wherein the causing step includes allowing the blade members to move radially outwardly into contact with the surrounding tissue.

5. The method of claim 1, wherein the barrier includes a stent structure spring biased in a radially outward direction, and wherein the causing step includes

allowing the stent structure to move radially outwardly into contact with the surrounding tissue.

6. The method of claim 1, wherein the barrier includes a conformable material, and wherein the causing step includes positioning the conformable material into contact with surrounding tissue.

7. The method of claim 6, wherein the conformable material includes an inflatable bladder.

8. The method of claim 7, wherein the causing step includes inflating the bladder into contact with the surrounding tissue.

9. The method of claim 7, wherein the causing step includes inflating the bladder and then positioning the bladder into contact with the surrounding tissue.

10. The method of claim 6, wherein the conformable material is a foam material.

11. The method of claim 1, wherein the barrier includes a proximal rim formed on the prosthetic device, the rim having an inverted position extending within the prosthetic device and a non-inverted position, wherein

the securing step includes, with the rim in the inverted position, connecting a portion of the rim to the tissue; and

the causing step includes moving the rim to the non-inverted position.

12. The method of claim 1, wherein the method includes causing the barrier to maintain contact with the surrounding tissue during movement of the stomach or expansion of the prosthetic device.

13. The method of claim 1, wherein the prosthetic device is a satiation pouch, and wherein the proximal opening is larger than the exit port.

14. A medical device positionable within a gastro-esophageal junction region of a patient having an esophagus and a stomach, the medical device comprising:

a prosthetic device having a proximal opening and an exit port, a proximal portion of the prosthetic device positionable within the gastro-esophageal junction region such that the proximal opening is in substantial alignment with the esophagus; and

a barrier attached to a proximal portion of the prosthetic device, the barrier defining a central passage at least partially aligned with the proximal opening of the prosthetic device, the barrier positioned to contact surrounding tissue substantially around its circumference when the prosthetic device is positioned within the gastro-esophageal junction region and to substantially maintain said contact despite movement of the surrounding tissue.

15. The medical device of claim 14, wherein the barrier includes a wall of flexible webbing.

16. The medical device of claim 15, wherein the wall further includes a resilient spring structure connected to the flexible webbing.

17. The medical device of claim 14, wherein the barrier includes a plurality of spring members defining the central passage and spring biased in a radially outward direction.

18. The medical device of claim 14, wherein the barrier includes a stent structure spring biased in a radially outward direction.

19. The medical device of claim 14, wherein the barrier is a conformable structure.

20. The medical device of claim 19, wherein the conformable structure is an inflatable bladder.

21. The medical device of claim 19, wherein the conformable structure includes foam material.

22. The medical device of claim 14, wherein the barrier includes a proximal rim formed on the prosthetic device and anchors attached to the rim, the rim moveable between an inverted position in which the rim extends within the interior of the prosthetic device and in which the anchors are in first position, and a non-inverted position in which the rim is removed from the interior of the proximal device and in which the anchors are in a second position, the second position being more distal than the first position.

23. The medical device of claim 14, wherein the barrier is adaptable in response to movement of the surrounding tissue to maintain said contact between the barrier and the surrounding tissue.

24. A method of treating obesity in a patient having an esophagus, a stomach, and a gastro-esophageal junction region, the method comprising the steps of:

providing a pouch having a proximal opening and an exit port, the exit port being smaller than the proximal opening;

further providing a barrier having a central passage at least partially aligned with the proximal opening;

attaching the pouch to tissue of the gastro-esophageal region of the patient and causing the barrier device to contact tissue substantially around its circumference;

causing the patient to ingest food, the ingested food passing from the esophagus through the central passage and proximal opening into the interior of the pouch, the barrier minimizing passage of food from the esophagus around the exterior of the pouch.

25. The method of claim 24, wherein the barrier includes flexible webbing defining the central passage.

26. The method of claim 25, wherein the flexible webbing includes a resilient spring structure, and wherein the causing step includes allowing the spring structure to move radially outwardly, carrying the webbing into contact with the surrounding tissue.

27. The method of claim 24, wherein the barrier includes a plurality of spring members defining the central passage and spring biased in a radially outward direction, and wherein the attaching step includes allowing the blade members to move radially outwardly into contact with the surrounding tissue.

28. The method of claim 24, wherein the barrier includes a stent structure spring biased in a radially outward direction, and wherein the attaching step includes allowing the stent structure to move radially outwardly into contact with the surrounding tissue.

29. The method of claim 24, wherein the barrier includes a conformable material, and wherein the attaching step includes positioning the conformable material into contact with surrounding tissue.

30. The method of claim 29, wherein the conformable material includes an inflatable bladder.

31. The method of claim 30, wherein the attaching step includes inflating the bladder into contact with the surrounding tissue.

32. The method of claim 30, wherein the attaching step includes inflating the bladder and then positioning the bladder into contact with the surrounding tissue.

33. The method of claim 29, wherein the conformable material is a foam material.

34. The method of claim 24, wherein the barrier includes a proximal rim formed on the prosthetic device, the rim having an inverted position extending within the prosthetic device and a non-inverted position, wherein:

the attaching step includes, with the rim in the inverted position, connecting a portion of the rim to the tissue, and then moving the rim to the non-inverted position.

35. The method of claim 24, wherein the method includes causing the barrier to maintain contact with the surrounding tissue during movement of the stomach or expansion of the pouch.

36. A method of positioning a prosthetic device in a body cavity region defined by a circumferential wall, comprising the steps of:

providing a prosthetic device having a proximal opening and a distal opening, a passage extending between the proximal and distal openings, and a barrier on a proximal portion of the prosthetic device;

distending a circumferential wall of a body cavity region;

positioning the prosthetic device adjacent to the disentended circumferential wall; and

releasing the circumferential wall from the distended positioning, allowing the released wall to circumferentially contact the barrier, the barrier encouraging passage of substances through the passage by minimizing passage of body fluid around an exterior of the prosthetic device.

37. The method of claim 36, wherein the circumferential wall is flared from a proximal portion to a distal portion.

38. The method of claim 36, further comprising the step of attaching the prosthetic device to the circumferential wall using an attachment device.

39. The method of claim 37, wherein the circumferential wall is a wall of a proximal stomach, and wherein the barrier encourages passage of ingested food from an esophagus through the passage of the prosthetic device.

40. A method of positioning a prosthetic device in a body cavity region defined by a flared circumferential wall, comprising the steps of:

providing a prosthetic device having a proximal opening and a distal opening, a passage extending between the proximal and distal openings, and a barrier on a proximal portion of the prosthetic device;

positioning the barrier in a collapsed position;

positioning the prosthetic device with the barrier adjacent to the flared circumferential wall; and

releasing the barrier from the collapsed positioning, allowing the released barrier to circumferentially contact the flared circumferential wall, the barrier encouraging passage of substances through the passage by minimizing passage of body fluid around an exterior of the prosthetic device.

41. The method of claim 40, further comprising the step of attaching the prosthetic device to the circumferential wall using an attachment device.

42. The method of claim 40, wherein the circumferential wall is a wall of a proximal stomach, and wherein the barrier encourages passage of ingested food from an esophagus through the passage of the prosthetic device.

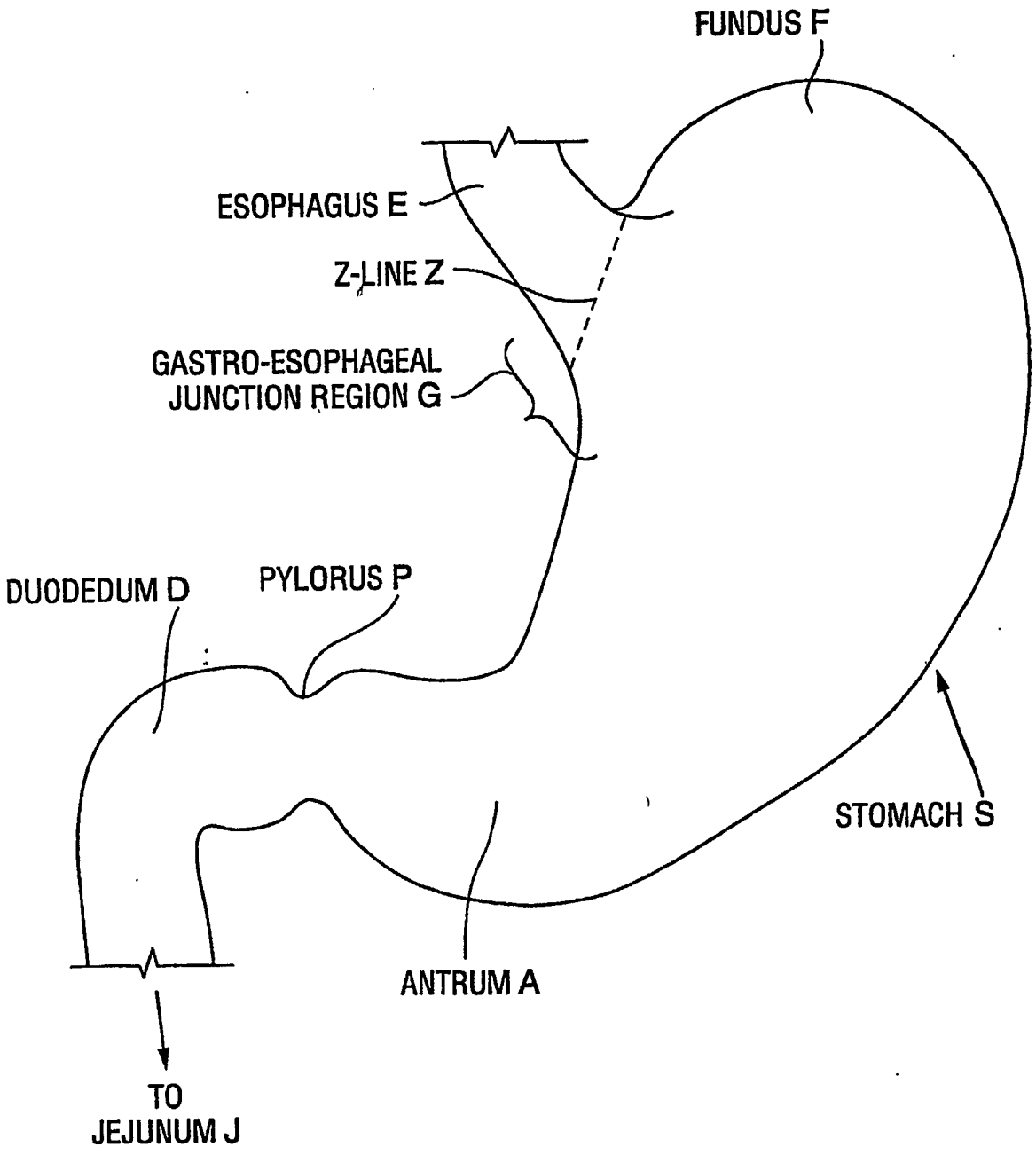
FUNDUS F
ESOPHAGUS E
Z-LINE Z
GASTRO-ESOPHAGEAL
JUNCTION REGION G
DUODEDUM D
PYLORUS P
STOMACH S
ANTRUM A
TO
JEJUNUM J

FIG. 1A

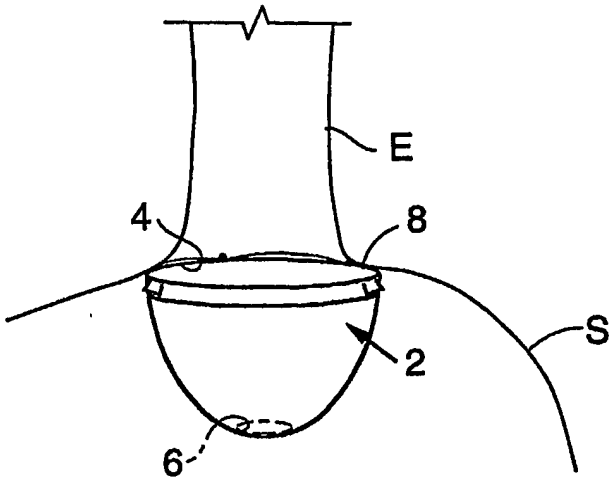

FIG. 1B

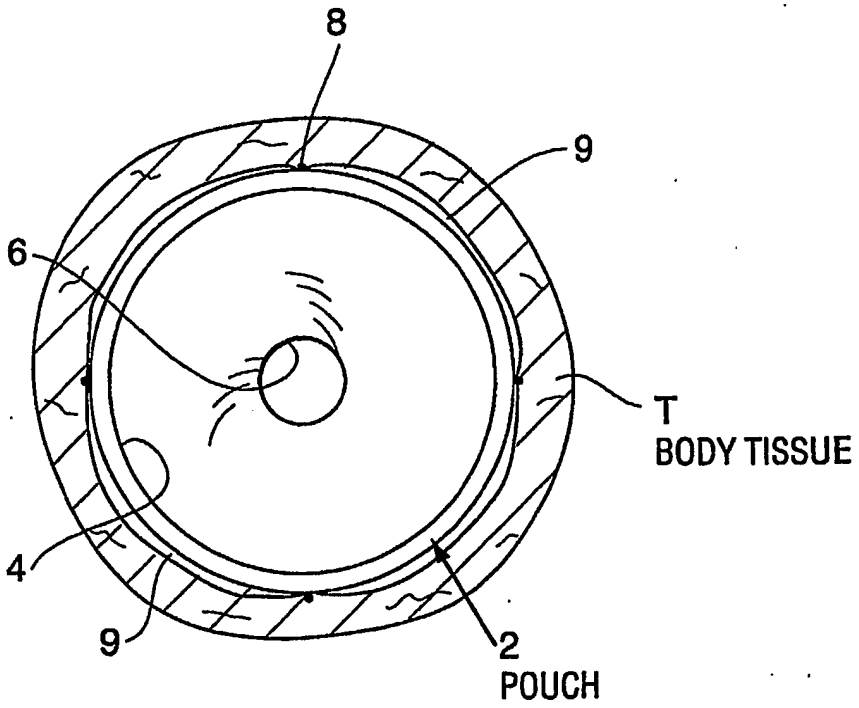

FIG. 1C

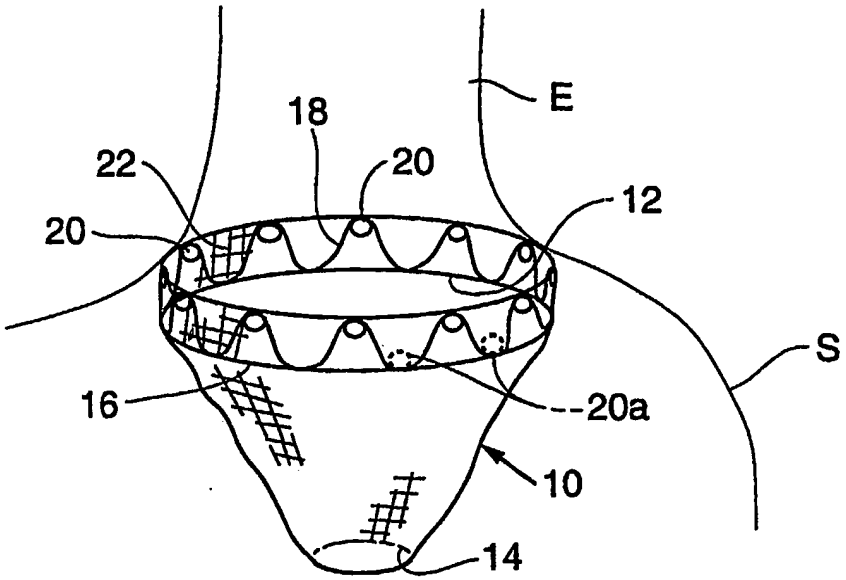

FIG. 2

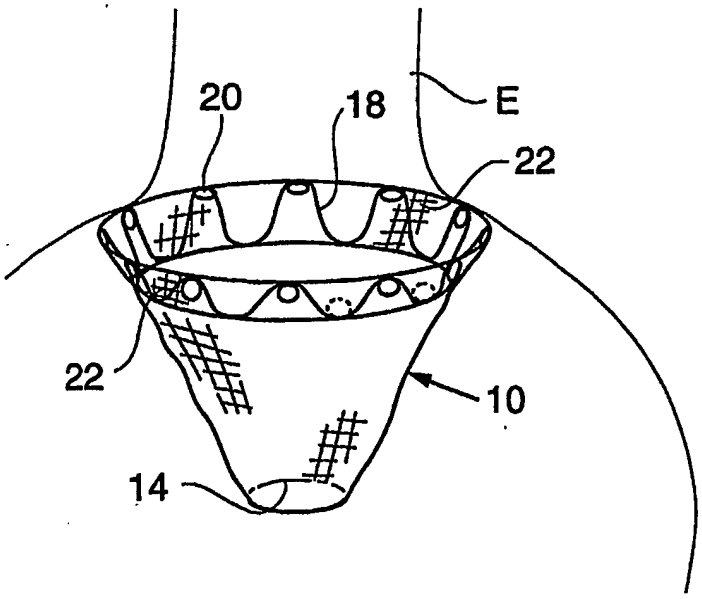

FIG. 3

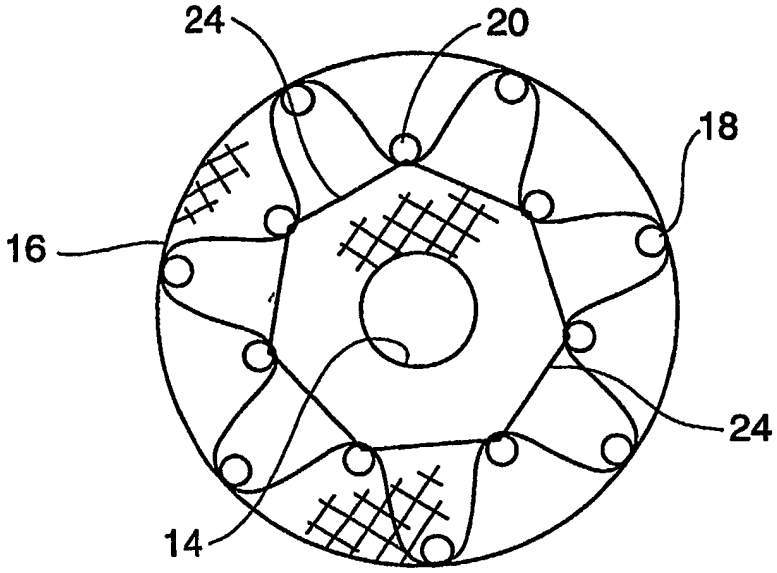

FIG. 4A

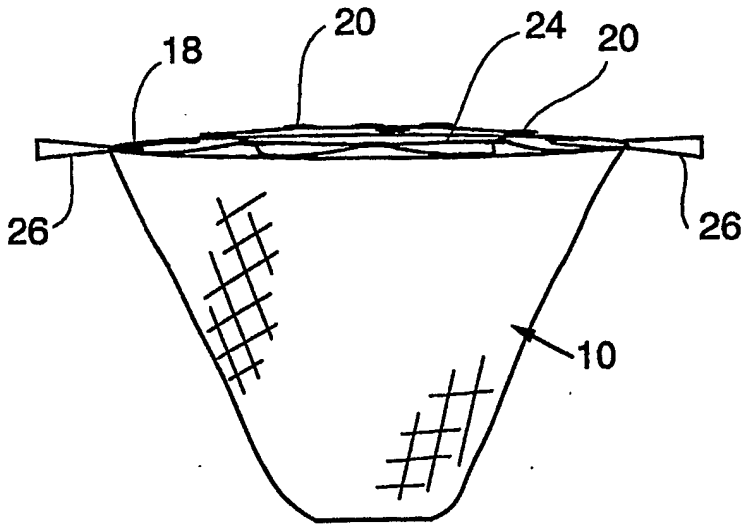

FIG. 4B

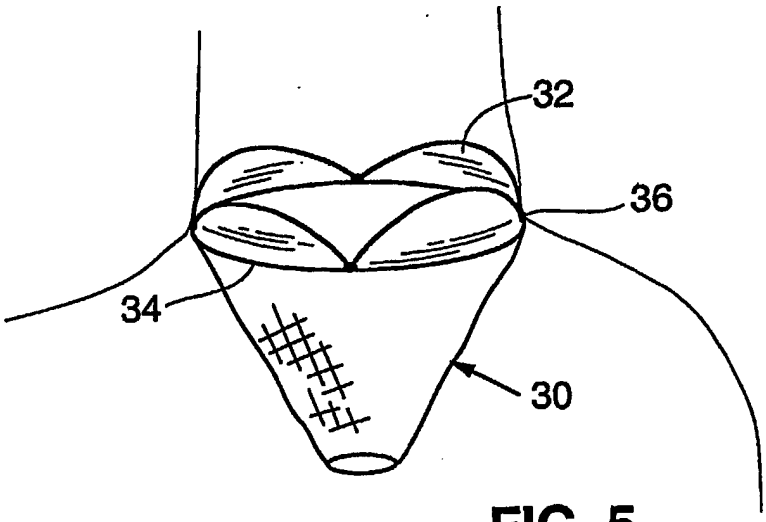

FIG. 5

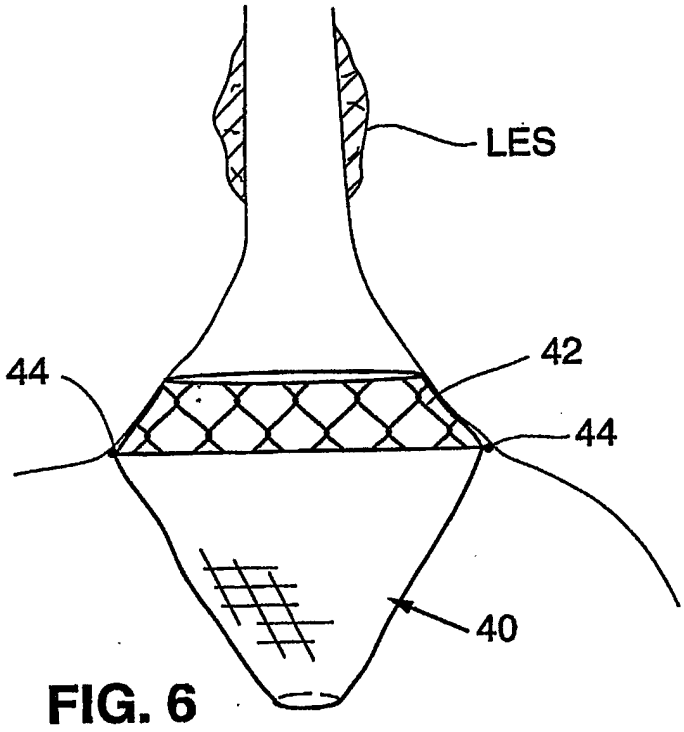

FIG. 6

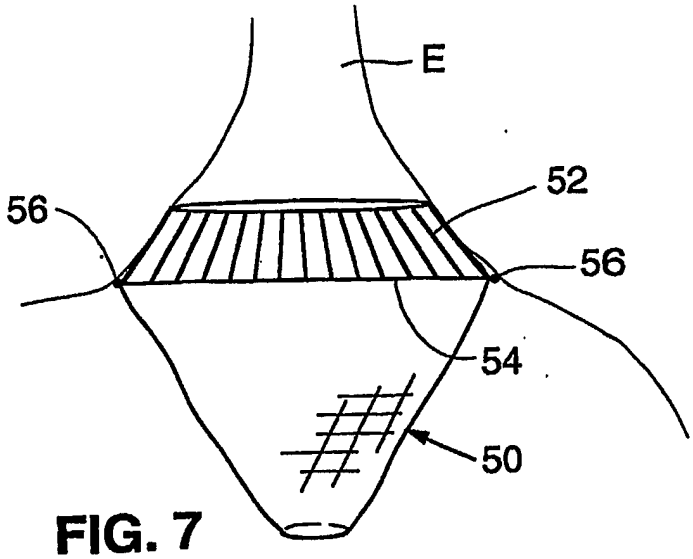

FIG. 7

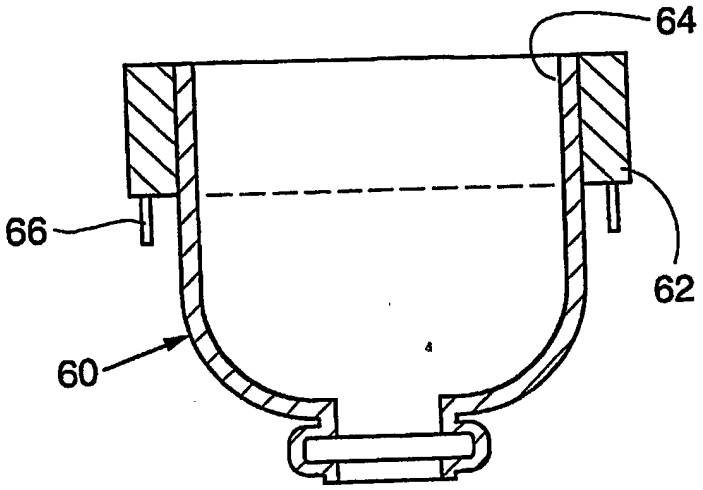

FIG. 8A

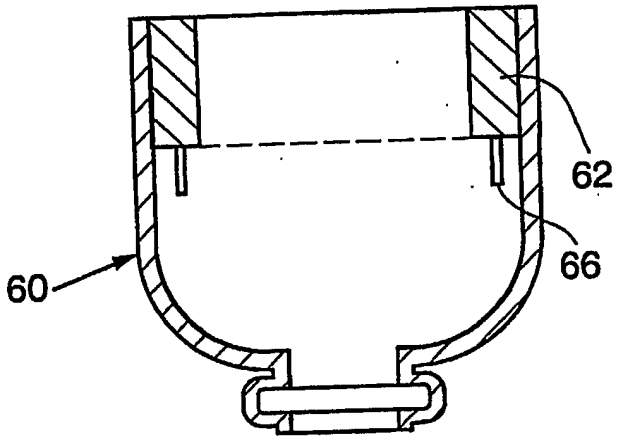

FIG. 8B

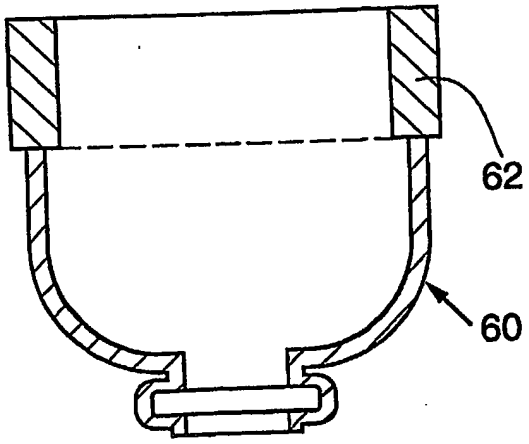

FIG. 8C

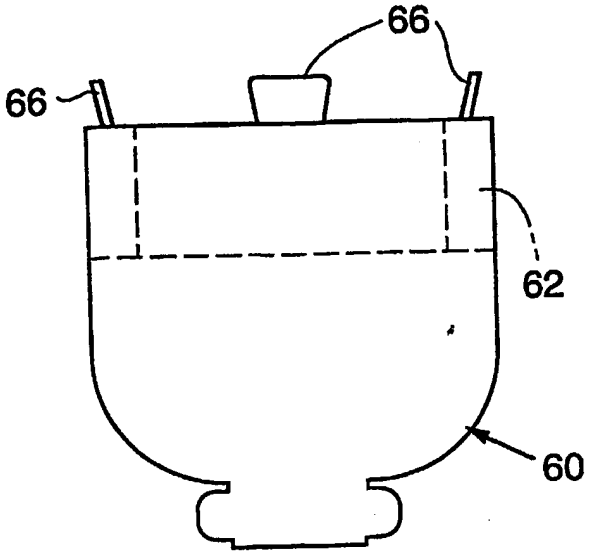

FIG. 9A

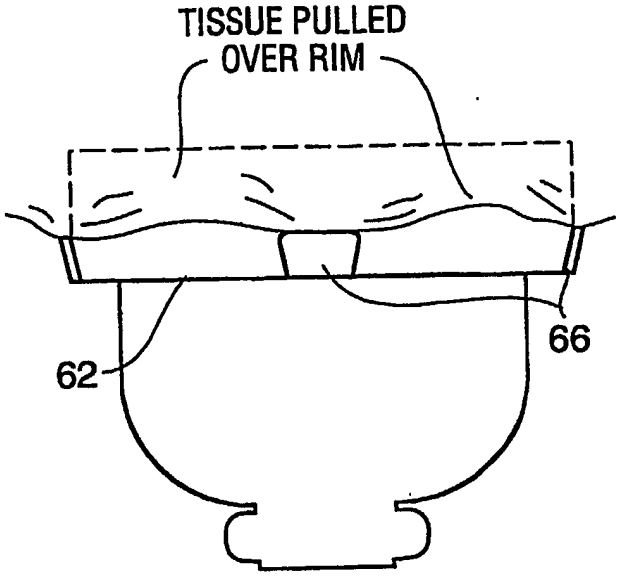

FIG. 9B

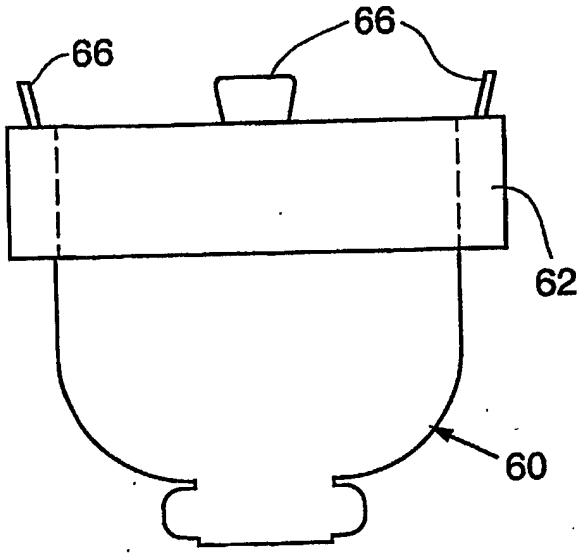

FIG. 10A

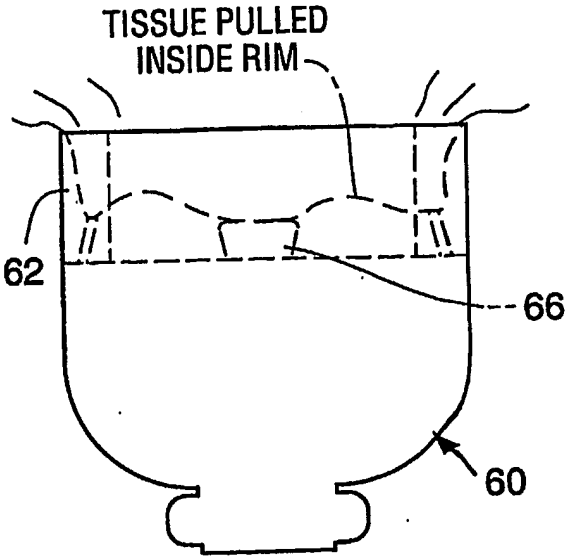

FIG. 10B

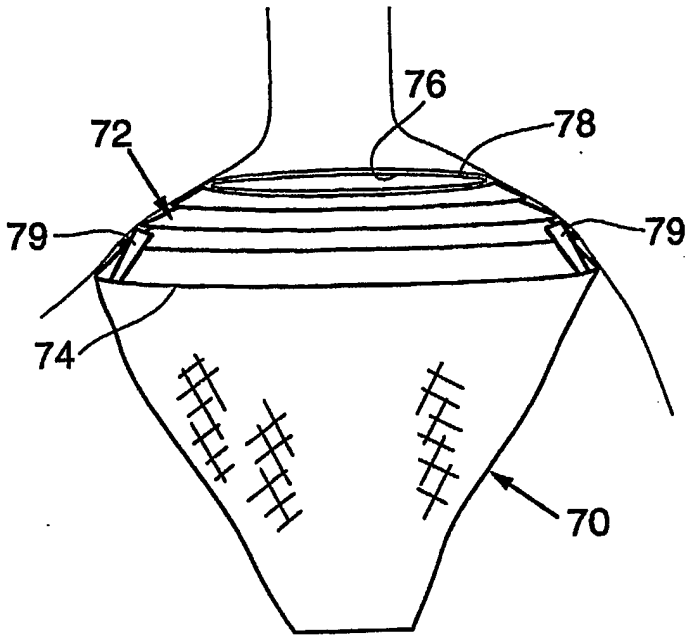

FIG. 11

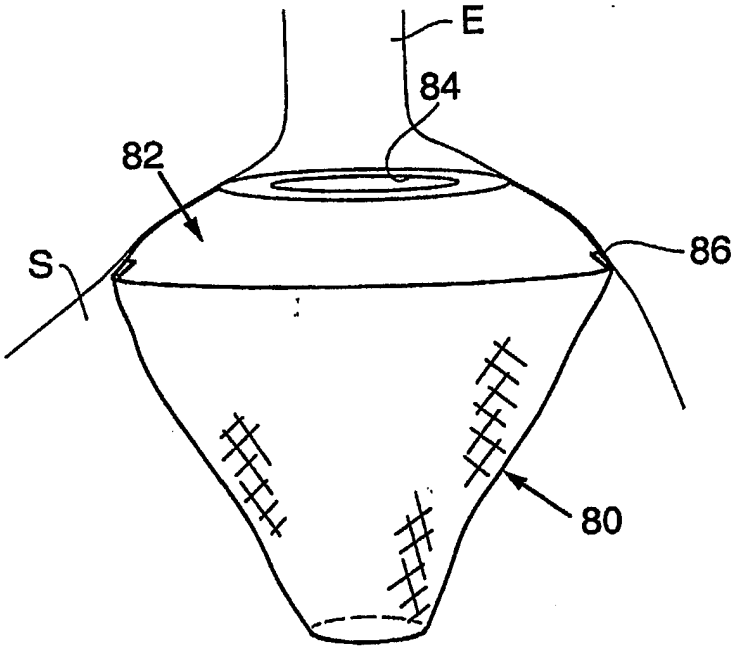

FIG. 12

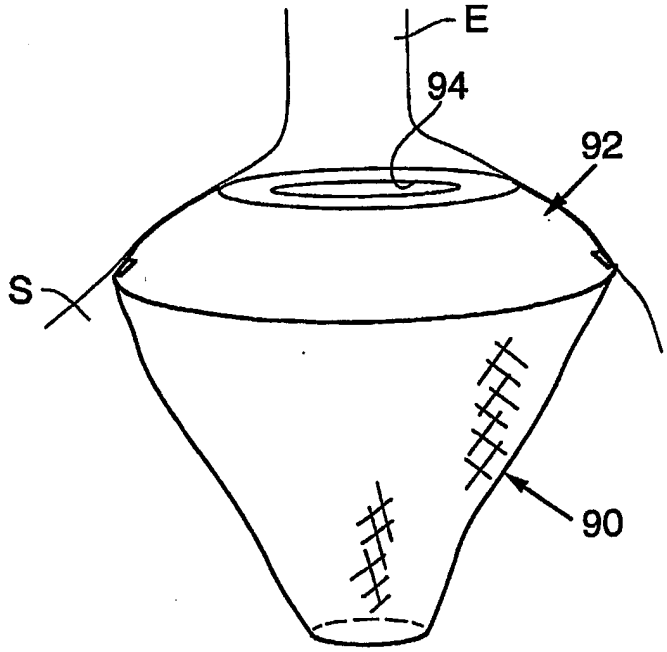

FIG. 13

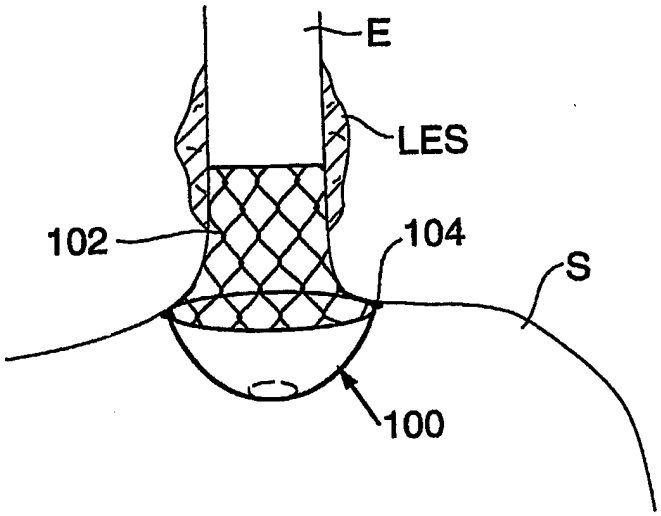

FIG. 14

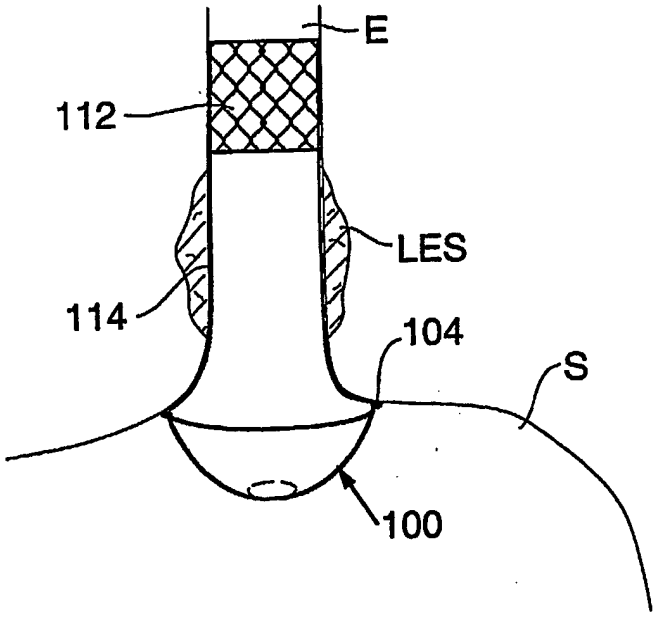

FIG. 15

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F2/04 A61F5/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2001/020190 A1 (TAYLOR THOMAS V) 6 September 2001 (2001-09-06)	14-19, 21,23
A	paragraphs '0044!,'0045! figure 2A	20,22
X	US 6 264 700 B1 (KILCOYNE JOHN ET AL) 24 July 2001 (2001-07-24) the whole document	14
X	EP 0 775 471 A (SCHNEIDER EUROP AG) 28 May 1997 (1997-05-28) the whole document	14
X	US 5 861 036 A (GODIN NORMAN) 19 January 1999 (1999-01-19) the whole document	14

-/--

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
8 March 2004	29/03/2004

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Franz, V

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 314 473 A (GODIN NORMAN J) 24 May 1994 (1994-05-24) the whole document ---	14
X	US 4 846 836 A (REICH JONATHAN D) 11 July 1989 (1989-07-11) the whole document -----	14

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 03/33605

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 1-13,24-42
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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